

[Our new endocrine clinic is monitoring estradiol levels in transgender male patients \(female to male\) and asked if our standard estradiol immunoassay is appropriate to use in this setting. What do you recommend?](#)

written by CAP TODAY
March 14, 2023

February 2023—Using gender-affirming hormone therapies is increasingly common in transgender and nonbinary populations, and monitoring hormone concentrations may help provide optimal outcomes for these patients.



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[What is the most specific serologic test for diagnosing IgG4-related disease?](#)

written by CAP TODAY
March 14, 2023

A. February 2023—IgG4-related disease (IgG4-RD) is a fibroinflammatory disease that can affect any organ and was first recognized as a unique clinical entity in 2003. The most affected organs include the pancreas, bile duct, major salivary glands, lacrimal glands, retroperitoneum, and lymphatic ducts. Key features of the disorder include elevated serum IgG4 concentrations, neoplastic-like swelling of the affected organs, as shown on an imaging test, specific histopathological characteristics on immunostaining, as well as a good response to treatment with glucocorticoids.

FDA expands approval for Ventana PD-L1 (SP263) assay

written by CAP TODAY
March 14, 2023

March 13, 2023—Roche announced that the FDA has approved the Ventana PD-L1 (SP263) assay as a companion diagnostic to identify non-small cell lung cancer patients eligible for treatment with Libtayo, a PD-1 inhibitor therapy developed by Regeneron.

Agilent announces global distribution agreement with Proscia

written by CAP TODAY
March 14, 2023

March 10, 2023—Agilent Technologies announced a multiyear distribution agreement with Proscia to offer a comprehensive digital diagnostic pathology system, combining Agilent's pathology staining solutions with Proscia's Concentriq Dx enterprise pathology platform.

FDA clears Abbott TBI lab-based blood test

written by CAP TODAY
March 14, 2023

March 9, 2023—Abbott has received FDA clearance for its Alinity i laboratory traumatic brain injury blood test.

Siemens and Sysmex sign OEM agreement

written by CAP TODAY
March 14, 2023

March 8, 2023—Siemens Healthineers signed a global OEM agreement on hemostasis products with Sysmex Corp.

BioMérieux Vidas Kube gets CE mark

written by CAP TODAY
March 14, 2023

January 2023—BioMérieux announced the CE marking of its Vidas Kube, a next-generation automated immunoassay system for the company's Vidas range. The system features a stackable and modular benchtop design and is compatible with the existing routine test menu covering emergency and critical care, immunochemistry, and infectious diseases. The commercial launch is planned in selected countries at the beginning of the year, extending gradually to the rest of the world during the second quarter.



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Roche launches antibody to identify PRAME protein expression

written by CAP TODAY
March 14, 2023

January 2023—Roche has launched its Anti-PRAME (EPR20330) Rabbit Monoclonal Primary Antibody to identify PRAME protein expression in tissue samples from patients who are suspected of having melanoma. Studies suggest that the detection of PRAME expression by immunohistochemistry complements findings from routinely used tests and enables more informed clinical decisions and improved patient outcomes, according to a company press release.



General Data launches LaserTrack Flex

written by CAP TODAY

March 14, 2023

January 2023—General Data Healthcare launched its LaserTrack Flex cassette printer. The Flex has a footprint of 13" L × 19" W and a capacity that starts at 480 cassettes, with each magazine holding 80 cassettes; it can be upgraded to hold up to 800 cassettes. The standard configuration prints on the face of the cassette and can be upgraded to also print on one or both sides. Cassettes can be loaded on the right or left side of the printer.



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EKF handheld hemoglobin analyzer with POC connectivity

written by CAP TODAY

March 14, 2023

January 2023—EKF Diagnostics' DiaSpect handheld hemoglobin analyzer now connects securely to EKF Link, the company's point-of-care middleware. DiaSpect is also now equipped with Bluetooth and internal storage for 4,000 tests and QC results, as well as the capability to provide a calculated hematocrit value alongside the hemoglobin result. Test results are stored and accessed securely on a centralized platform.



